REMARKS

This Amendment is in response to the Office Action dated July 11, 2003. Reconsideration and allowance is respectfully requested.

Claims 1-3 and 5-7 have been rejected under 35 U.S.C. § 103(a) as obvious over WO 98/24427 to Hunter in combination with Lasic, Journal of Controlled Release, 1997. The rejection is respectfully traversed.

The Hunter reference discloses on page 8, line 15 to page 9, line 2 a long list of active agents including epothilones.

Hunter also discloses a myriad of carriers that begin on page 26 and continue until page 33. This 8 page list includes liposomes as carriers on page 32.

Further, there are 43 Examples in Hunter spanning 97 pages; neither epothilones nor liposomes are mentioned.

The Examiner has selected epothilones from the long list of actives and liposomes from the long list of carriers without any support or suggestion for these particular selections. There is nothing in this reference to suggest that epothilones be picked form the long list of actives; and there is nothing to suggest that liposomes be selected from the 8 page list of carriers. In addition, there is nothing to suggest that these elements be combined to form the claimed composition.

The Examiner has merely selected the elements of the claimed invention from 2 long lists without any suggestion that these particular elements be selected. Since there is no suggestion in the prior art of the presently claimed compositions, it was only with hindsight, after seeing applicants claims that the examiner came to the conclusion the epothilones could be formulated with liposomes. Such hindsight is impermissible.

In addition, based on the very broad disclosure of Hunter, undue experimentation would be necessary to arrive at an epothilone-liposome formulation as claimed in the present invention.

Accordingly, the present claims cannot be obvious from Hunter; and the secondary reference, Lasic, does not provide the missing disclosure necessary to render the claims

obvious. Lasic teaches the benefits of liposomes with certain drugs, including toxic drugs, however there is no mention or suggestion of epothilones. Without such suggestion, the present claims cannot be obvious from a combination of Hunter and Lasic.

Since neither Hunter nor Lasic suggest the combination of epothilones and liposomes, the present invention cannot be obvious from Hunter alone or a combination of Hunter and Lasic and the rejection should be withdrawn.

Claims 1-7 have been rejected under 35 U.S.C. § 103(a) as obvious over WO 98/24427 to Hunter alone or in combination with Lasic, Journal of Controlled Release, 1997 and further in view of United States Patent No. 5,683,715 to Boni. The rejection is respectfully traversed.

As discussed above, neither Hunter nor Lasic, alone or in combination, suggest epothilone-liposomal formulations; Boni does not provide the missing disclosure or suggestion. Boni is directed to taxanes, and there is no suggestion or teaching of epothilones. Accordingly, for all the reasons discussed above, the present claims cannot be obvious from these references alone or in combination and the rejection should be withdrawn.

In view of the foregoing remarks, applications respectfully submit that the present claims are in condition for allowance which action is earnestly solicited.

Respectfully submitted,

Novartis Corporate Intellectual Property One Health Plaza, Building 430 East Hanover, NJ 07936-1080 (862) 778-7898

Date: November 10, 2003

Lydia T. McNally Attorney for Applicants Reg. No. 36,214

<u>Abstract</u>

The present invention provides pharmaceutical liposomal compositions comprising epothilones.